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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,043	06/15/2005	Anil Kishen	1304.P004US/LYH/ay	8341

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EXAMINER	
HOBBS, MICHAEL L	

ART UNIT	PAPER NUMBER
1797	

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07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,043	KISHEN ET AL.	
	Examiner	Art Unit	
	MICHAEL HOBBS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-24* is/are pending in the application.

4a) Of the above claim(s) *13 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12 and 14-19* is/are rejected.

7)☐ Claim(s) _ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 04/14/2009 has been considered and entered for the record. Applicant's amendment overcomes the objection to the claims in paragraph 3 of the Office Action mailed on 10/14/2008.

2. Claims 13 and 20-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 1-12 and 14-19 are pending further examination upon the merits.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248).

8. Erb discloses for claim 1 a sensor that includes a fiber optic cable (fiber 12) which has had the cladding striped off of one portion of the fiber (col. 10 lines 22-23) and covered with a coating (col. 10 lines 33-36; Table 1). Also, the sensor chamber contains a fluorophore or precursor which combines with the target molecule to measure the extent of the immuno-chemical reaction (col. 6 lines 42-44 & 49-51). While Erb discloses using a flurophore, the reference is silent regarding the furophore or precursor being immobilized within the coating.

9. Cramp discloses a fiber optic sensor with a bonded dye or precursor that is used for detecting changes in a chemical or physical property by using a chromophore bound to a porous substrate. For claim 1, Cramp discloses that the chromophore coating extends into a porous substrate (col. 2 lines 33-35; Abstract) which is being interpreted as "within the coating". This type of coating whereby the dye extends into the substrate provides the added advantage of increased sensitivity for the sensor (col. 2 lines 35-37). This also overcomes the sensitivity problem of a surface bound dye that would normally

be overcome by a more sensitive detector or a longer length of optical fiber (col. 2 lines 28-30). Based on the advantage of this coating, one of ordinary skill in the art would find it obvious to employ the embedded dye of Cramp within Erb in order to obtain the predictable result of increasing the sensitivity of the sensor.

10. For claim 2, the unclad portion of the fiber discloses by Erb is being interpreted as being "declad" and for claims 3 and 4, Erb further discloses using two or a plurality of unclad portions on two fiber segments (col. 10 lines 20-24). With regards to claim 5, Erb discloses measuring the fluorescence from the immuno-chemical reaction by a detector (detector 16; col. 7 lines 26-30). For claim 10, the fluorophore combines with the target molecule as discussed above.

11. Regarding claim 6 and 7, Erb is silent regarding the coating being glass and also being porous and thin.

12. Cramp discloses for claim 6 that the dye is deposited on a porous glass layer (col. 2 lines 51-53) which is being interpreted as a film. For claim 7, the glass layer is being interpreted as being thin. Therefore, it would have been obvious for one of ordinary skill in the art to employ the glass layer suggested by Cramp in order to have a surface for the dye of Erb. The suggestion for doing so at the time would have been to provide a surface that enables the chromophore molecules to be bounded by silane agents within the interstices of the porous layer (col. 2 lines 59-61).

13. For claim 11, Erb discloses a sensor that includes a fiber optic cable (fiber 12) which has had the cladding striped off of one portion of the fiber (col. 10 lines 22-23) and covered with a coating (col. 10 lines 33-36; Table 1). Also, the sensor chamber

contains a fluorophore or precursor which combines with the target molecule to measure the extent of the immuno-chemical reaction (col. 6 lines 42-44 & 49-51). Erb discloses a light source (source 14) that "co-operates" with the first end of the optical fiber (fiber 12; col. 7 lines 8-10) and includes a monitoring means or detector that is fully capable of "co-operating" with the unclad portion of the fiber.

14. For claim 11, Cramp discloses that the chromophore coating extends into a porous substrate (col. 2 lines 33-35; Abstract) which is being interpreted as "within the coating". This type of coating whereby the dye extends into the substrate provides the added advantage of increased sensitivity for the sensor (col. 2 lines 35-37). This also overcomes the sensitivity problem of a surface bound dye that would normally be overcome by a more sensitive detector or a longer length of optical fiber (col. 2 lines 28-30). Based on the advantage of this coating, one of ordinary skill in the art would find it obvious to employ the embedded dye of Cramp within Erb in order to obtain the predictable result of increasing the sensitivity of the sensor.

15. For claim 12, Erb discloses that an evanescent field (field 42) or wave is generated from the input light (col. 7 lines 17-19).

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248) and in further view of Hirschfeld et al. (US 4,558,014).

17. Erb and Cramp are silent regarding the precursor as specified in claim 9.

18. Hirshfeld discloses an assay apparatus that uses fluorescent material such as a dye that has been incorporated into a coating on an optical fiber. For lcaim 9, Hirschfeld discloses that the dye (57) used with the fiber is methylene blue (col. 8 line 66 – col. 9 line 1). Furthermore, methylene blue is known within the art and it would have been obvious for one of ordinary skill in the art to employ methylene blue as suggested by Hirschfeld within the sensor of Erb and Cramp in order to have an indicator attached to the surface of the fiber. The suggestion for doing so at the time would have been in order to have a fluorescent agent that is an immunologically inert dye (col. 8 lines 46-48).

19. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248) and in further views of Dhadwal et al. (US 2003/0152308 A1) and Ligler et al. (US 5,496,700).

20. For claim 14, Erb discloses the step of using a sensor that includes a fiber optic cable (fiber 12) which has had the cladding striped off of one portion of the fiber (col. 10 lines 22-23) and covered with a coating (col. 10 lines 33-36; Table 1). Also, the sensor chamber contains a fluorophore or precursor which combines with the target molecule to measure the extent of the immuno-chemical reaction (col. 6 lines 42-44 & 49-51). Erb discloses using a light source (source 14) that "co-operates" with the first end of the optical fiber (fiber 12; col. 7 lines 8-10) and includes a monitoring means or detector that receives the light from one end of the fiber. The sensor of Erb is "located" or placed

within a flow tube that allows the fiber to come into contact with a fluid sample (col. 15 lines 10-14) and the light or electromagnetic output is analyzed by a light energy detector (detector 16; col. 6 lines 20-24). Erb is silent regarding the steps of monitoring the emission from the unclad portion of the fiber and determining the presence of microorganisms.

21. Cramp does not explicitly state that the light from the unclad portion of the fiber is monitored by a detector.

22. Dhadwal discloses a capillary wave guide that carries a fluid sample that fluoresces when an excitation beam is sent down the axial length of the capillary tube. For claim 14, Dhadwal discloses that light is delivered to the optical fluid connector by an optical fiber and includes a collector constructed of optical fibers perpendicular to the capillary ([0018]). These fibers collect the light emitted from the fluid sample and send the light to data processing equipment for measuring and analyzing the collected fluorescent data ([0046]). Also, Dhadwal demonstrates that the technique of monitoring electromagnetic output with a sensor that is perpendicular to the axis of a fiber or tube was known at the time of the instant application. Further, the steps of using this orientation of the sensor would have been recognized by the skilled artisan as an alternative to receiving the light from the sample through the distal ends of the optical fiber and would minimize the noise within the data sent to the processing unit. Therefore, it would have been obvious to one of ordinary skill in the art to employ the steps of using the detector of Dhadwal within the measuring steps of Erb and Cramp in order to obtain the predictable result of detecting a target molecule.

23. However, Erb, Cramp and Dhadwal are silent regarding the step of testing for a microorganism. However, the combined testing steps of Erb, Cramp and Dhadwal can be adapted to test or identify microorganisms within the fluid sample.

24. Ligler discloses a rapid detection and identification of microorganisms that for claim 14 includes the steps of using a coated optical fiber waveguide for detecting microorganisms (col. 3 lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art to employ the step of testing for microorganisms as suggested within the optical fiber sensor of Erb, Cramp and Dhadwal. The suggestion for doing so at the time would have been in order to capture and detect a microorganism of interest (Abstract).

25. Claims 15, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248) and in further views of Dhadwal et al. (US 2003/0152308 A1), Ligler et al. (US 5,496,700) and Soller (US 5,582,170).

26. Erb, Cramp, Dhadwal and Ligler do not explicitly state that the step of monitoring the electromagnetic output is a spectroscopic method or and adsorption analysis of the output. However, the steps of monitoring the output can be interpreted as a spectroscopic method. Also, the monitoring methods of Erb, Cramp, Dhadwal and Ligler can be adapted by the skilled artisan to be a spectroscopic monitoring method since such analytical methods are known within the art.

27. Soller discloses fiber optic sensor for measuring nitric oxide that includes for claims 15 and 16 monitoring the adsorption of NOX into hemoglobin by using adsorption spectroscopy (col. 3 lines 54-56) and the analysis of the data is by adsorption analysis and identifying the peaks for identifying changes of the NO concentration (col. 5 lines 57-60). For claim 17, the data is sent to a computer (computer 9) that the light output and input of the system (col. 8 lines 48 and 49). Therefore, it would have been obvious to one of ordinary skill in the art to employ the technique of using adsorption spectroscopy as suggested by Soller with the testing steps of Erb, Cramp, Dhadwal and Ligler in order to obtain the predictable result of monitoring the target molecule bound to the fiber.

28. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248) and in further views of Dhadwal et al. (US 2003/0152308 A1), Ligler et al. (US 5,496,700) , Soller (US 5,582,170) and Carter et al. (US 4,608,344).

29. Erb, Cramp, Dhadwal, Ligler and Soller are silent regarding a computer or programmable device that can identify the genus or species of a microorganism.

30. Carter discloses an optical wave guide that for claim 18, includes the step where an electronic unit (unit 62) receives data from a photomultiplier tube that has been amplified and provides a computation that provides the concentration of an unknown microorganism according to usual means which implies the use of an algorithm (col. 18 lines 35-38). Using this method would be obvious to one of ordinary skill in the art to

employ the programmable device of Carter in order to identify the target microorganism of Erb, Cramp. Dhadwal, Ligler and Soller. The suggestion for doing so at the time would have been in order to have a microprocessor for computing the measured data and comparing this data with stored references (col. 18 lines 12-14).

31. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erb et al (US 5,854,863) in view of Cramp et al. (US 4,560,248) and in further views of Dhadwal et al. (US 2003/0152308 A1), Ligler et al. (US 5,496,700) , Soller (US 5,582,170), Carter et al. (US 4,608,344) and Prober et al. (US 5,306,618).

32. Erb, Cramp, Dhadwal, Ligler, Soller and Carter are silent regarding a programmable device that ascribes an index to the identified feature and provide an overall index for a sample.

33. Prober discloses a system for DNA sequencing that includes a computer (controller 52) that operates the overall system. For claim 19, Prober discloses for claim 19 that initializes data arrays (arrays R(I) & T(I)) and acquires the data points for each array from the detectors. This input is recorded on a data file, the index of each array is incremented, and a new data point is record. This is repeated based on a pre-determined number of data points that are to be acquired by the system (Fig. 4a). However, Prober does not sum up these data points to generate a contamination value. This summation of the data points would be obvious to the skilled artisan since this is a standard mathematical operation and computer of Prober can be easily modified to perform this step. Therefore, it would be obvious to one of ordinary skill in the art to

employ the indexing and data file suggested by Prober within the combined steps of Erb, Cramp, Dhadwal, Ligler, Soller and Carter in order to store the obtained features to a data file. The suggestion for performing this step at the time of the invention would have been in order to obtain the predictable result of being able to recall specific features based on where that feature has been indexed in the data file.

Response to Arguments

34. Applicant's arguments with respect to claims 1-7, 9-12 and 14-19 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection is in view of Cramp which discloses a dye or precursor that is bound to a glass layer or film and therefore corrects the deficiencies within Erb.

Conclusion

35. Claims 1-7, 9-12 and 15-19 are rejected.

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797